

IN THE CLAIMS

1-14 (Cancelled)

15. (Withdrawn) Process for the preparation of the complexes as defined in claim 1, comprising the following steps:

(a) paroxetine, as free base or as salt, a cyclodextrin or a cyclodextrin derivative and water are mixed;

(b) the obtained mixture is stirred in order to obtain an homogeneous solution or dispersion and stirring is continued until formation of the complex; and

(c) the water is partially removed in order to obtain a solid complex with the desired water content.

16. (Withdrawn) Process as claimed in claim 15 characterised in that paroxetine is used as a free base.

17. (Withdrawn) Process as claimed in claim 15 characterised in that paroxetine is used as a salt.

18. (Withdrawn) Process as claimed in claim 15 characterised in that step b) is carried out by mechanical stirring or by ultrasounds.

19. (Withdrawn) Process as claimed in claim 15 characterised in that step c) is carried out by freeze drying, drying under vacuum or under an inert gas flux.

20. (Withdrawn) Process as claimed in claim 15 characterised in that in step c) a solid complex with a water content of between 1 and 20% by weight is obtained.

21. (Withdrawn) Process as claimed in claim 20 characterised in that said water content is between 2 and 15% by weight.

22. (Withdrawn) Process as claimed in claim 16 characterised in that step a) is carried out according to the following steps:

- a₁) a cyclodextrin or a cyclodextrin derivative is added to water;
- a₂) the solution or dispersion of step a₁) is kept under stirring for a time from 30 to 180 minutes at a temperature between 25° and 50°C; and
- a₃) paroxetine base is dispersed in the solution or dispersion of step a₂).

23. (Withdrawn) Process as claimed in claim 17, characterised in that said step a) is carried out according to the following steps:

- a₁) paroxetine base is salified with an organic or inorganic acid; and
- a₂) a cyclodextrin or a cyclodextrin derivative is added under stirring to the salified paroxetine.

24. (Withdrawn) Process as claimed in claim 16 characterised in that step c) is carried out according to the following steps:

- c₁) the dispersion of step b) is cooled and maintained at a temperature between 4°C and 20°C for 1 to 20 hours;
- c₂) the precipitate obtained in step c₁) is recovered by filtration; and
- c₃) the solid product recovered in step c₂) is dried under vacuum or under an inert gas flux until the desired water content is reached.

25. (Withdrawn) Process for the preparation of complexes as claimed in claim 1 comprising slowly adding paroxetine base in the form of an oily liquid to a cyclodextrin or to a cyclodextrin derivative in a mixer for powders or in an ultrasonic mixer and continuing the stirring for a time ranging from 3 to 24 hours at a temperature from 25 to 50 °C.

26. (Cancelled)
27. (Cancelled)
28. (Withdrawn) Therapeutical method for the treatment of patients suffering from depression or Parkinson's disease or other pathologies curable with paroxetine consisting of the administration of a complex as defined in claim 1, in an amount corresponding to 5-40 mg per day of paroxetine by oral way and corresponding to 1-20 mg per day of paroxetine parenterally.
29. (Currently Amended) An inclusion complex of paroxetine, as a free base or as a salt, with a cyclodextrin [or with a cyclodextrin derivative].
30. (Previously Presented) The inclusion complex as claimed in claim 29, wherein it is in the form of a flowing powder, it has a greater stability in comparison with the non-complexed paroxetine, organic solvents are absent, it has a higher solubility in water with respect to the non-complexed paroxetine and a DSC profile different from that of the corresponding non-complexed paroxetine or paroxetine salt.
31. (Previously Presented) The inclusion complex as claimed in claim 30, wherein ethanol is absent.
32. (Previously Presented) The inclusion complex as claimed in claim 29, having a water content of between 1 and 20% by weight.
33. (Currently Amended) The inclusion complex as claimed in claim 32, having a water content [is] between 2 and 15% by weight.
34. (Previously Presented) The inclusion complex as claimed in claim 29, wherein the cyclodextrin is selected from the group consisting of α , β and γ -cyclodextrin.

35. (Previously Presented) The inclusion complex as claimed in claim 34,
wherein the cyclodextrin is a β -cyclodextrin.
36. (Cancelled)
37. (Cancelled)
38. (Previously Presented) The inclusion complex as claimed in claim 29,
wherein the salt of paroxetine is a salt with an organic or inorganic acid.
39. (Previously Presented) The inclusion complex as claimed in claim 38,
wherein said organic or inorganic acid is selected from the group consisting of acetic acid, maleic
acid, hydrochloric acid and methanesulfonic acid.
40. (Previously Presented) The inclusion complex as claimed in claim 39,
wherein said acid is hydrochloric acid.
41. (Currently Amended) The inclusion complex as claimed in claim 29,
wherein the molar ratio between paroxetine and said cyclodextrin [or cyclodextrin derivative]
ranges from 1:0.25 to 1:20.
42. (Currently Amended) The inclusion complex as claimed in claim 41,
wherein the molar ratio between paroxetine and said cyclodextrin [or cyclodextrin derivative]
ranges from 1:0.5 to 1:2.
43. (Previously Presented) A pharmaceutical composition containing as an
active substance a pharmaceutically effective dose of an inclusion complex as defined in
claim 29, in mixture with pharmaceutically acceptable diluents or excipients.
44. (Previously Presented) The pharmaceutical composition as claimed in
claim 43 in solid or liquid form, for oral and for parenteral administration.

45. (New) An inclusion complex of paroxetine, as a free base or as a salt, with a cyclodextrin derivative, wherein said inclusion complex is in the form of a flowing powder, has a greater stability in comparison with the non-complexed paroxetine, is free from organic solvents, has a higher solubility in water with respect to the non-complexed paroxetine and a DSC profile different from that of the corresponding non-complexed paroxetine or paroxetine salt.

46. (New) The inclusion complex as claimed in claim 45, wherein ethanol is absent.

47. (New) The inclusion complex as claimed in claim 45, wherein said salt of paroxetine is a salt with an organic or inorganic acid.

48. (New) The inclusion complex as claimed in claim 47, wherein said organic or inorganic acid is selected from the group consisting of acetic acid, maleic acid, hydrochloric acid and methanesulfonic acid.

49. (New) The inclusion complex as claimed in claim 48, wherein said acid is hydrochloric acid.

50. (New) The inclusion complex as claimed in claim 45, wherein the molar ratio between paroxetine and said cyclodextrin derivative ranges from 1:0.25 to 1:20.

51. (New) The inclusion complex as claimed in claim 50, wherein the molar ratio between paroxetine and said cyclodextrin derivative ranges from 1:0.5 to 1:2.

52. (New) The inclusion complex as claimed in claim 45, wherein said cyclodextrin derivative is selected from the group consisting of heptakis (2,6-di-O-methyl)- β -cyclodextrin, heptakis (2,3,6-tri-O-methyl)- β -cyclodextrin, monosuccinyl-heptakis(2,6-di-O-methyl)- β -cyclodextrin, 2-hydroxypropyl- β -cyclodextrin, sulphated cyclodextrin and cyclodextrin containing aminoalkyl groups.

53. (New) The inclusion complex as claimed in claim 52, wherein said cyclodextrin derivative is the 2-hydroxypropyl- β -cyclodextrin.

54. (New) A pharmaceutical composition containing as an active substance a pharmaceutically effective dose of an inclusion complex as defined in claim 45, in mixture with pharmaceutically acceptable diluents or excipients.

55. (New) The pharmaceutical composition as claimed in claim 54, in solid or liquid form, for oral and for parenteral administration.